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Danny Charles Bowman

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EXAMINER

GAKH, YELENA G

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/737,185	Applicant(s) BOWMAN ET AL.	
	Examiner Yelena G. Gakh, Ph.D.	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2009 and 26 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 38 and 40-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 38 and 40-49 is/are rejected.
- 7) ☒ Claim(s) 45-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner reopens the prosecution of the case as the result of the remand and order from the Board of Appeals from 01/26/10. Amendment to the claims filed on 06/24/09 is acknowledged. Claims 1-21, 38 and 40-49 are pending in the application.

Response to Amendment

2. In response to the amendment the examiner objects to claims 45-47 as not further limiting the subject matter of the parent claim, clarifies rejection of the claims under 35 U.S.C. 112, second paragraph, adds "claim interpretation", and maintains rejection of the claims over the prior art.

Claim Objections

3. Claims 45-47 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite the subject matter, which is not related to the structure of the product recited in the parent claim.

Double Patenting

4. Applicant is advised that should claim 1 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Interpretation

5. Claims 1-17, 38, 40-43 and 45-49, directed toward a system, recite a diagnostic (toxicology) specimen system comprising a population of vessels (which are obviously identical) with wireless electronic tags directly attached to the vessels. The claims additionally recite that the vessels are either distributed or are transported between the facilities.

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According to 35 U.S.C. 101, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

The only patentable subject matter in the claims is a plurality of vessels with the electronic tags directly attached to them. Locations of these vessels at different facilities, including the recitation for a group of vessels being transported between the facilities, are not the limitations for the structure of the patentable manufacture, i.e. a plurality of vessels with the electronic tags, and therefore are not considered by the examiner as anyhow limiting the structure of the manufacture, which is a vessel with the electronic tag. Thus, the locations do not bear any patentable weight.

6. Regarding interpretation of the claim language, the "electronic tag" is disclosed in the specification, as the following: "[t]he electronic memory tag 3 includes a carrier label 4 which has a front face 5 and a rear face 6". Therefore "the electronic memory tag" can be considered to be equivalent to the "custody form" comprising RFID chip 102 disclosed by Petrick (US 6,535,129). Furthermore, since the electronic tag is more than electronic chip, according to the specification, and the claims do not specify the structure of the electronic memory tag, the examiner interprets this term in the broadest sense, e.g. as any label or any support that carries electronic chip and is directly attached to the vessel. Therefore, Berney's support with electronic chip, which is directly attached to the vessel, is considered to be "electronic memory tag".

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-17, 38, 40-43 and 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite a population of vessels located at different locations (e.g. a vessel distribution facility, a specimen collection facility, a specimen testing laboratory facility) with some specimen being transported between the facilities. The vessels themselves have a specific

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structure comprising a wireless electronic memory tag for non-contact storage and retrieval information directly attached thereto.

It is not clear from the claims, which patentable weight the locations of the vessels have in the claims. It is not clear, whether the population of vessels having the same structure, but locating at a different location, then those indicated in the claims, will be patentably distinct from the system recited in the claims? It is not clear, whether in the case, when e.g. all population is located at a present moment at one location, and not distributed through all locations - will this be patentably distinct from the claimed population? In other words - will moving the population of the similar vessels to a different location (e.g. transporting them to a different country) change the patentability of the presently claimed subject matter?

The Applicants are respectfully referred to the following excerpt from MPEP:

"§2171 Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph:

The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

- (A) the claims must set forth the subject matter that applicants regard as their invention; and
- (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process.

The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner

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should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 Bd. App. 1984)"

Furthermore:

"§2172 Subject Matter Which Applicants Regard as Their Invention:

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int 'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993)."

In the present case "the language of the claims is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement", and therefore rejection a rejection of the claim under 35 U.S.C. 112, second paragraph, is appropriate.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. **Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41 and 45-48** are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129 B1).

Petrick discloses a method and a business form attached to a collection vessel for establishing a chain of custody; the invention comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3,

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lines 18-36), as well as the information corresponding to the various forms 102: “in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or **automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206)**. This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106” (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: “as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to “follow” the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip” (col. 4, lines 45-57). The method for recording information includes providing a population of biomedical specimen containers, which a collection custodian receives from a distribution location (see Figure 1), collecting a specimen from a donor in the specimen container at the specimen collection facility and electronically storing information about the specimen, donor, and/or test to be performed in the specimen on the electronic memory tag (col. 3 and 4).

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11. **Claims 1, 6-7, 9, 14-15, 19, 21, 40-41 and 45-48** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). The electronic label 50 is a part of the electronic tag 3, which is directly attached to the vessel and is fixed there for the purpose of transporting the vessel between facilities. "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing reducing error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

The location of the vessels according to the Claim Interpretation is not limiting the structure of the vessels and therefore does not have any patentable weight. The vessels can be located anywhere and transported wherever they should be transported without changing their

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structure. The expression "said labels are mounted on supports being provided to fix said labels onto said test tubes during the time of analysis" obviously refers to analysis in general. The system inherently includes an electronic database accessible from the specimen collection facility for storing data entered at the collection facility. Exchanging information between the collection of vessels and a remote location inherently comprises an electronic network. Berney discloses a method for recording information about a diagnostic specimen by providing a population of biomedical specimen containers with wireless electronic memory tags, distributing these containers to a specimen collection facility, collecting samples and electronically storing information about the specimen, donor, and/or tests to be performed, as it is indicated previously. Moving the test tubes from the collection facility (a desk where the samples are taken) to the analysis site is what Berney discloses for his population of the test specimen tubes with electronic tags.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney.

While Petrick or Berney do not specifically disclose shipping vessels with the electronic memory tags from "vessel distribution facility" to the specimen collection facility, it would have been totally obvious for any person of ordinary skill in the art to have prepared vessels with the tags shipped to the medical labs for collecting analysis from the "vessel distribution facility", where these vessels are prepared and have some data (e.g. the date of attaching the tag) to be stored in the tag memory.

14. **Claims 5, 8 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of the prior art disclosed by Leuenberger (US 5,314,421).

The disclosure of Petrick and Berney is provided above.

Although Petrick or Berney do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who

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discloses blood plastic containers indicates in the “Background of the Invention”: “of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, *manufacturer's product code* and *lot number*, etc.” (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional step in diagnostic environment, and upgrading this system by electronically storing this information is obvious for Petrick's or Berney's test tubes, which are specifically designed for handling such information.

15. **Claims 16-17, 20, 42-44 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

The disclosure of Petric and Barney is provided above.

Petrick or Berney do not particularly teach encoding electronic signature in the electronic tag, although Petrick specifically indicates “tester's signature” in form 102, Fig. 3B. The signature of the “person under concern” (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a “tokenless identification system for authorization of electronic transactions and electronic transmissions” (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Petrick's or Berney's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

16. **Claims 2 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

The disclosure of Barney is provided above.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

17. **Claims 3-4 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens et al. (EP 1,004,359 A2).

The disclosure of Berney is provided above.

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Berney does not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises “a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms” (col. 2, paragraph [0013]). In one of the embodiments, “the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives” (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney’s container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to “create a link between the container, the patient and the test request forms”, or any other forms associated with using this container.

18. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman (US 5,135,313).

The disclosure of Berney is provided above.

Berney does not specifically disclose the vessel with a tamper-indicating seal.

Bowman discloses a chain-of-custody tamper-indicating seal for a bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney’s specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. “so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal” (col. 1, lines 7-8).

19. **Claim 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens and Leuenberger.

The disclosure of Barney is provided above.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). “Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc.” (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that “it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels”.

RD 421048 A discloses a “method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system” (Title). “The identification (ID) tags could be self-powered or passive **transponder** type”. “The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS” (Abstract). “A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent” (Advantage).

It would have been obvious for anyone of ordinary skills in the art to modify Berney container (test tube) by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in “logging, identification, tracking and chemical management” of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A

Berney in view of RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises “a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms” (col. 2, paragraph [0013]). In one of the embodiments, “the first two of

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the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives” (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for any person of ordinary skill in the art to add a label with a barcode and provide the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to “create a link between the container, the patient and the test request forms”, or any other forms associated with using this container

Berney in view of RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier and the product (container) information.

Leuenberger in his “Background of the Invention” related to the blood pack labels indicates, concerning blood plastic containers, “of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc.” (col. 1, lines 13-18).

It would have been obvious for any person of ordinary skill in the art to add information on identity of suppliers as indicated by Leuenberger, because this conventional information is always provided with the manufacture products, especially the test containers, and because the identity of the supplier and the vessel may assist in the proper handling the vessel.

20. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens, Leuenberger the same way it is applied to claim 8 above, and further in view of Hoffman or Fukuzaki.

Berney in view RD 421048 A, Stevens and Leuenberger do not particularly teach encoding electronic signature in the electronic tag, although the signature of the “person under concern” (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a “tokenless identification system for authorization of electronic transactions and electronic transmissions” (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Berney- RD 421048 A-Stevens-Leuenberger's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

Response to Argument

21. Applicant's arguments filed on 06/24/09 have been fully considered but they are not persuasive.

Arguments regarding rejections of the pending claims under 35 U.S.C. 112, second paragraph, are considered, but are moot in light of clarified explanation of indefiniteness and unclarity of the claim language provided in the present Office action. The Applicants are expected to provide explanation of what they consider to be a patentable subject matter of the pending claims directed toward the system and to answer questions regarding different situations with different locations of the groups of vessels having the same structure as those recited in the claims. Are the vessels with the same structure but in different locations than those recited in the claims patentably distinct from the system recited in the claims?

The Applicants' reference to various US patents which recite the word "location" in different context is not convincing, since the claimed subject matter of provided patents is not related to locations of identical vessels. The patentable subject matter in the instant application regarding the system of the plurality of vessels is the structure of the vessel, which comprises the electronic tag.

Rejection of claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38 40-41 and 45-48 under 102(e) as being anticipated by Petrick's US 6,535,129.

As the examiner indicated in the previous Office actions, she considers instant invention and Petrick's invention disclosed in US 6,535,129 patentably indistinct. The instant invention claims a collection of vessels with wireless electronic memory tags. The electronic memory tag,

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according to the instant specification, "includes a carrier label 4". This is equivalent to Petrick's business form comprising a wireless electronic device (tag). Petrick's tag is adhered to the specimen *or to a container containing a specimen* (claim 7). It is a clear anticipatory recitation for claim 1 of the pending application. Location of the vessels does not bear any patentable weight, as was indicated previously. "A container" recited by Petrick is obviously "a plurality of containers", with singular and plural forms conventionally inter-changeable in claims recitation. Therefore, the Applicants' claim is not novel in view of the Petrick's claimed invention.

Petrick claims a business form with the wireless identification device adhered to the specimen container, and the Applicants recite vessels with wireless tags and labels with identification bar code attached to vessels (see e.g. claims 3, 12, etc.). According to the Applicants specification,

"[a]n electronic memory tag 3 is affixed to an exterior surface of the vessel 1. An enlarged front view of a preferred embodiment of the electronic memory tag 3 is shown in FIG. 2. The electronic memory tag 3 includes a carrier label 4 which has a front face 5 and a rear face 6. Preferably, the front face 5 is imprinted with an identification bar code 7. A text area 8 is also provided for printing, typing, or writing pertinent information on the front face 5 of the carrier label 4. A detail view of the rear face 6 of the carrier label 4 is shown in FIG.3. An electronic memory device 9 is attached to the rear face 6. Alternatively, the invention may include a separate electronic memory tag 3 and a second printed label having a bar code 7 imprinted thereon (not shown)." (page 11).

Thus, the recitation of the Applicants' claims comprises both embodiments, i.e. having electronic tag and a label on a single form and on separate forms, and reads on any of them. The first embodiment is identical to the claimed Petrick's subject matter. Also, having the tags and labels both on the same "business form" or on separate forms would have been an obvious modification for an alternative embodiment, with both type of forms for biological specimen containers notoriously well known in the art. Therefore, Petrick's invention would be either anticipatory for, or an obvious modification of the Applicants' invention. Attachment of the wireless tag to the form (paper) inherently provides a visual indication of "de-associating" the tag from the form, when it occurs. Petrick in claim 7 recites attaching a wireless identification device directly to a specimen "*or a container containing the specimen*", with the second part of the recitation, which the Applicants for some reason forgot to mention.

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Regarding the method claims: in claim 8 Petrick recites establishing “chain of custody” using the wireless tag attached to the form and container, with the “chain of custody” for a biological specimen inherently comprising distributing, transferring and analyzing specimen in the containers at corresponding locations. The chain of custody comprises all these elements by definition. Therefore, the recitations of claim 8 of Petrick’s patent and that of claim 18 of the instant application are not patentably distinct.

This establishes two-way anticipating and/or obviousness of the instant invention and Petrick’s prior art, which makes them patentably indistinct.

Establishing patentable identity for the instant application and Petricks' invention makes the Declaration 1.131 improper in the present case, since according to MPEP § 1.131: “Prior invention may not be established under this section if ... the rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims *the same patentable invention* as defined in § 41.203(a) of this title, in which case an applicant may suggest interference pursuant to § 41.202(a) of this title”.

On pages 23-27 the Applicants perform their own two-way comparative analysis of the claimed inventions by Petrick and by the present Applicants.

The first Applicants' statement that the Applicants' claim 1 is novel over Petrick because it claims a population of collection vessels having members at different locations does not seem convincing. First, as it has been indicated by the examiner above, a population of collection vessels having members at different locations is patentably indistinct from one collection vessel that has exactly the same structure as the plurality of the population vessels. Second, Petrick's subject matter related to the business form comprising an electronic tag and attached to the vessel inherently comprises a plurality of such business forms attached to a plurality of vessels and located at different locations for the following reason. The subject matter of the Petrick's claimed invention is related to "establishing a chain of custody", as recited in claim 8. "The chain of custody" refers to handling a plurality of biomedical samples along the chain of custody, which inherently assumes handling a plurality of the biomedical containers located at corresponding locations along the "chain of custody". Thus, Petrick's *claimed* subject matter is not patentably distinct from the Applicants' claimed subject matter.

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As for the statement that "Applicants' claims is not even directed to similar subject matter", it appears that the Applicants cited the first three words from each claim to show a difference in the subject matter of the claimed inventions. The examiner does not consider this as a proper argumentation. As for the Petrick's electronic tag being attached to the form *vs.* the Applicants' electronic tag being attached to the vessel, the examiner refers the Applicants to their own disclosure, according to which "[t]he electronic memory tag 3 includes **a carrier label 4** [i.e. "a business form" in Petrick's terminology] which has a front face 5 and a rear face 6". Furthermore, according to the Applicants specification,

"[a]n electronic memory tag 3 is affixed to an exterior surface of the vessel 1. An enlarged front view of a preferred embodiment of the electronic memory tag 3 is shown in FIG. 2. The electronic memory tag 3 includes a carrier label 4 which has a front face 5 and a rear face 6. Preferably, the front face 5 is imprinted with an identification bar code 7. A text area 8 is also provided for printing, typing, or writing pertinent information on the front face 5 of the carrier label 4. A detail view of the rear face 6 of the carrier label 4 is shown in FIG.3. An electronic memory device 9 is attached to the rear face 6. Alternatively, the invention may include a separate electronic memory tag 3 and a second printed label having a bar code 7 imprinted thereon (not shown)." (page 11).

Thus, the recitation of the Applicants' claims comprises both embodiments, and reads on any of them, with the first embodiment totally identical to the claimed Petrick's subject matter.

As for the "vessel distribution facility", again, as soon as the tag is attached to the vessel, the location becomes the "vessel distribution facility".

As for the Applicants' analysis of the Applicants' claimed subject matter as the prior art to Petrick's claimed subject matter, the Applicants disclose in their specification two embodiments for the form comprising either two separate parts, one for the electronic tag and another one for providing other relevant information, or one part with the electronic tag attached to the form. Both embodiments read on the Applicants' claimed subject matter, with one of these embodiments being exactly the same as the subject matter claimed by Petrick. Furthermore, according to MPEP §2111,

"the pending claims must be "given their broadest reasonable interpretation consistent with the specification." >The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted

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by one of ordinary skill in the art.” *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must “conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.” 37 CFR 1.75(d)(1)."

The Applicants recite "electronic memory tag" directly attached to the vessel, with the electronic memory tag , according to the specification, comprising a carrier label 4, which is equivalent to Petrick's business form.

Therefore, the two-way claim analysis performed by the examiner meets the requirements established in *Winter vs. Fujita*.

The examiner believes that the further Applicants' analysis of the recited method in Petrick and in the instant application follows the same path as the one used for the apparatus claims. The examiner would like to indicate again, that as soon as Partrick's electronic tag becomes attached to the vessel, with the electronic tag containing any information (since the information is not specified in claim 18 of the instant application), the vessel becomes located in the "vessel distribution location". The "chain of custody" assumes transferring vessels between different locations of the chain, with corresponding information added to the tags.

The examiner is not quite sure, as to what the Applicants mean by the following statement: "The Examiner insists that Appellant and Petrick claim the same patentable invention without showing that Petrick's claims anticipate or render Appellant's claims obvious. No doubt the Examiner has not done so because the task is impossible: Appellant is not claiming the same patentable invention as Petrick." This statement is not clear, because it appears that that's exactly what the examiner did in all previous and the present Office actions, i.e. demonstrated how Petrick's claims anticipate the Applicants' claims.

Regarding different classification of the instant application and Petrick's patent, as the examiner indicated in the previous Office actions, “the Applicants’ statement that just a mere classification of inventions in different classes unambiguously indicates that they are patentably distinct, is not quite correct, which is confirmed by the Applicants’ own application. While it contains two separate groups of claims directed to a specimen system and a method for recording information, classified in different classes, they are not patentably distinct, and therefore were not restricted”. Furthermore, many classes have an overlapping subject matter. Classification of the inventions in different classes is never a mere basis for restriction requirements, contrary to

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the Applicants' statement. It is only a patentable distinction between different inventions, which makes the proper basis for the restriction requirements.

In Responding to the Examiner's Comments, the Applicants refer again to the language of instant claims and those of Petrick's US patent, trying to find verbatim similarities. MPEP does not state that the claims should have word-to-word recitation in order to invoke interference. Instead, MPEP states (see above) that the claims may not only be non-anticipatory, but they can be obvious variations of each other, the condition, which does not require exact similarity of the claim language between the patent and the application.

Furthermore, it is well known that "[t]he Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004).

Petrick discloses a business form comprising RFID logger, attached to the vessel, which is *exactly* the same as "electronic memory tag", which comprises label 4, attached to the vessel. Moreover, exact the same "electronic memory tag" in Petrick's invention and in the instant application renders it inherent that "said wireless identification device being associated with a form of such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form" the vessels of the instant application.

As to the Applicants' reference to their own disclosure regarding description of the "electronic memory tag as "one of the embodiments", in which " the electronic memory tag 3 *can include* a carrier label", the examiner would like to remind the Applicants, that the exact excerpt of their disclosure reads as the following: "[t]he electronic memory tag 3 *includes* a carrier label 4 which has a front face 5 and a rear face 6". No other embodiments are provided in the specification. The examiner reads the claims in light of the specification, exactly how is taught by MPEP. Furthermore, the examiner is not aware of any case law or MPEP paragraph which requires ALL embodiments of the invention to be the same in both potentially interfering cases.

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As to not mentioning the word "biology" in Petrick's claim 8, the examiner wonders, whether the word "biological" is not related to the word "biology" ("a biological sample collection container"), and whether the applicants' claims actually refer to "biology", rather than to "biological samples".

The Applicants state that they are not claiming the form in the instant claims. This is not correct, since the electronic tag, according to the Applicants' own disclosure comprises label 4, which is equivalent to the form. As to the lack of discussion of how the container gets to the collection custodian, it is possible to assume that this is not the collection custodian, who produces such collection containers.

The Applicants referring to the examiner's interpretation of the claims in light of the specification as erroneous seems to contradict MPEP rules.

Rejection of the pending claims as being anticipatory over Berney (page 31 of the Appeal Brief).

The discussion of the prior art of Berney starts on page 34 (with the title provided on page 31). The major focus of the Applicants' discussion of the Berney's disclosure is that Berney's electronic tag is attached to the vessel at the time of analysis and is temporary. In fact, as soon as the vessel receives the tag attached to the vessel, the location of the vessel becomes "the vessel distribution facility". The fact that the spring-loaded mount is removable does not mean that it is removed, the same way as the label used by the Applicants can be removably attached to the vessel, which does not mean that it will be removed. Moreover, since the specific structure of the electronic tag is not recited in the claims, and it can be any support carrying the electronic chip, the whole Berney's support with the chip can be considered as "the electronic tab", which is directly attached to the vessel and stays during all procedures and transportation of the vessels.

As for such limitations as vessel locations, the examiner already expressed her view on the patentability weight of such claims limitations, not mentioning that all these locations are inherent for all custody chains of medical samples.

Regarding claim 19, it is totally unapparent, how the Applicants draw their conclusion on that Berney's labels are attached in the lab and are removed in the lab on the basis of the excerpt from Berney's patent provided by the Applicants. While the Applicants indicated that the

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examiner erroneously reads the claims in light of the specification, the Applicants in fact interpret the specification to such extent, that the interpretation does not even remotely resembles the disclosure.

Even if Berney's tags were attached in the lab, the bench in the lab on which the vessels with attached tags are located is the "vessel distribution facility", the vessels are transferred to the table (collection site) and into the analyzer (analysis site).

Claim 44 is rejected as being obvious over both Petrick and Berney for the reason indicated above.

Regarding Applicants claim 21, the examiner does not recall, where specifically "she also acknowledged that Berney does not disclose transporting vessels to a specimen-testing laboratory. But, she reasons, since transporting vessels is conventional medical practice, one of ordinary skill would have transported Berney's vessels, "because it allows tracking the vessels using Berney's inventive electronic tags on the specimen vessels."

It appears from the Applicants' arguments related to all dependent claims rejected under obviousness-type rejection, that the major statement of the Applicants is that Petrick and Berney is not the prior art for the pending claims, which were rejected over Petrick and Berney on anticipatory basis. It also appears that the Applicants' refer to the secondary references as lacking all limitations of the independent claims rejected over Petrick and Berney on anticipatory basis, which is not a proper way of arguing obviousness type rejections. It does not appear that the Applicants have any additional arguments regarding obviousness type rejections.

Regarding combination of Petrick's or Berney's teachings of using electronic tags for storing electronic information and Leuenberger's teaching of disclosing information on manufacturers and products, it would have been obvious for any routineer in the art to store information disclosed by Leuenberger in Petrick's or Berney's electronic tags for an obvious reason of improving storing information in electronic tags *vs.* paper forms.

Rejection of claim 8 does not seem to be properly analyzed, since the examiner has used multiple references for the claim rejection, which were not even considered by the Applicants in their arguments.

Regarding claims 3-4 and 11-12 the Applicants remark that it would not have been obvious for any person of ordinary skill in the art to use Stevens' label, because it disturbs Barney's

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invention of eliminating all manual entry to the form. The examiner considers these arguments not persuasive for the following reasons: first, Barney did not mention anywhere that “all” useful information should be written in the electronic tags, and, second, such label secures the identity of the vessel in the case when, e.g. the tag is lost, which would have been obvious for any routineer in the art.

As for modification of Barney’s tube with the tamper-indicating seal, disclosed by Bowman (Claim 38), such protection is necessary even when the samples are left in the same facility, since tampering is possible not only during transferring tubes with samples between facilities, but when they are stored at the same place.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Vickie Y. Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/7/2010

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797